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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/091,072	06/09/98	TIEMESSEN	H 4-100-8288/P
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001095 HM12/0608  
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EXAMINER

JONES, D

ART UNIT

PAPER NUMBER

1614

*5*

DATE MAILED: 06/08/99

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

09/091,072

Applicant(s)

Tiemessen

Examiner

Dwayne C. Jones

Group Art Unit

1614

☐ Responsive to communication(s) filed on \_\_\_\_\_

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 1-5 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 1-5 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*Dwayne C. Jones*  
**DWAYNE C. JONES**  
**PRIMARY EXAMINER**

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-5 are pending.
2. Claims 1-5 are rejected.

### ***Priority***

3. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in United Kingdom on January 19, 1996. It is noted, however, that applicant has not filed a certified copy of the 9601120.0 application as required by 35 U.S.C. 119(b).

### ***Information Disclosure Statement***

4. The information disclosure statement filed August 12, 1998 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed entered as Paper No. 2 on the jacket of the application, however, there is neither a copy of the IDS list nor is there a copy of the references in the application file.

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### *Specification*

5. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

#### **Arrangement of the Specification**

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
  - (b) **Cross-References to Related Applications.**
  - © Statement Regarding Federally Sponsored Research or Development.
  - (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
  - (e) Background of the Invention.
    - 1. Field of the Invention.
    - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
  - (f) Brief Summary of the Invention.
  - (g) **Brief Description of the Several Views of the Drawing(s).**
  - (h) Detailed Description of the Invention.
  - (I) Claim or Claims (commencing on a separate sheet).
  - (j) **Abstract of the Disclosure** (commencing on a separate sheet).
  - (k) Drawings.
  - (l) Sequence Listing (see 37 CFR 1.821-1.825).
6. This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bollinger et al. of EP 296,122 A2 possessing a publication date of December 21, 1988 in view of both Windholz, Editor of The Merck Index, 10th Edition, which has a publication date of July 21, 1986 and Osol, Editor of Remington's Pharmaceutical Sciences, 15th Edition having a publication date of June 11, 1976. Bollinger et al. teach of cyclosporins, in particular the especially preferred Compound No. 1.38 which is [3'-Desoxy-3'-oxo-MeBmt]1-[Val]2-cyclosporin, (as listed on page 10, lined 44-51 and Example H on page 26). Bollinger et al. teach that cyclosporins are useful in reversing resistance to chemotherapy, (see abstract). Bollinger et al. further teach that these cyclosporins can administered parenterally or intravenously, (see page 34, lines 1-12). The prior art reference of Bollinger et al. is silent to incorporation of oleic acid and ethanol. Windholz, Editor of The Merck Index, 10th Edition teach that it is well known in the art that oleic acid is pharmaceutical aid (solvent), (see page 6707 column 1). Osol, Editor of Remington's Pharmaceutical Sciences, 15th Edition, teach that ethanol is a well known solvent in pharmacy, (see pages 1252 and 1253). Since it is taught in the art that [3'-Desoxy-3'-oxo-MeBmt]1-[Val]2-cyclosporin can administered parenterally or intravenously and moreover that both oleic acid and ethanol are well established in the pharmaceutical art as pharmaceutical solvents, it would have been obvious to the skilled artisan to combine the above listed components in order to obtain an emulsion of the cyclosporin compound. The determination of solubility is well within the level of one having ordinary skill in

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the art, and the artisan would be motivated to determine optimum pharmaceutical solvents to generate the maximum effect of the drug. Hence, the above-stated references make obvious the instant invention.

9. Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Backlund et al. of WO 95/31969 which has an issue date of November 30, 1995. Backlund et al. teach of a pharmaceutical composition comprising an emulsion of a drug, particularly cyclosporin, with mono-, di-, or tri-glycerides of C<sub>8-20</sub> fatty acids, such as oleic acid, and also with phospholipids, (see abstract and pages 7-10). The claims differ from the reference by reciting a specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those of the claims, because an ordinary artisan would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as the genus as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merk & Co. Vs. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

#### *Duplicate Claims*

10. Applicant is advised that should claim 1 be found allowable, claim 5 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application

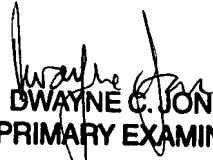
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are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4634.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
**DWAYNE C. JONES**  
**PRIMARY EXAMINER**

Tech. Ctr. 1614  
May 28, 1999